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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/938,428	08/23/2001	Eugene Michael Breznock		2577

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EUGENE M BREZNOCK
27956 STATE HIGHWAY 128
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EXAMINER

ROBERTS, PAUL A

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 07/30/2003

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/938,428

Applicant(s)

BREZNOCK, EUGENE MICHAEL

Examiner

Paul A Roberts

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 June 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Drawings

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the jackscrew, hydraulic cylinder, hydraulic pressure supply, ridges, and electric motor must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.
2. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 3, 4, 5, 9-11, and 16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. To provide enablement, the applicant must disclose and illustrate how to construct the claimed device. No explanation of how to implement a jack screw, ridges, or hydraulic drive on the applicant's punch was disclosed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 3, 5, and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not clear, based on the applicant's disclosure, what a jackscrew or ridges are.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 2, 8, 9, 10, 11, 13, 15, and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Young et al. "Young" US 5,827,316. Young discloses a punch with a cutting blade, a spring as the controlled force, and an anvil. The cutting blades rotate relative to the anvil while the cutting blades is being advanced toward the anvil. The tapered tip is element 54. As best understood, ridges are disclosed on item 54. They are capable of penetrating tissue and are inherently sharp enough to cut tissue. The ridges are disposed axially. Figure 1a, shows the ridges to be blunted.

6. Regarding claims 13, 15, and 17, while Young does not disclose the same method of use verbatim to the methods steps of claims 13, 15, and 17, the intended use of the Young device can be found in the opening lines of the column 1, where Young discloses this device is intended to be used as aortic punch. The aortic punch of Young would be inherently used as described in claims 13, 15, and 17.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Young et al.

“Young” ‘316 in view of Kramer et al. “Kramer” US 5868711. Young discloses all of claim 1 as described above but does not disclose that the device could be alternately powered by a hydraulic mechanism. As best understood, in light of no illustration or description of a hydraulic cylinder or hydraulic pressure supply, Kramer teaches a surgical punch utilizing a hydraulic cylinder or hydraulic pressure supply. Kramer also teaches that is well-known in the art to substitute a spring mechanism for a hydraulic mechanism on a surgical punch.

A number of driving forces may be employed to displace the piston 14. A pressurized fluid in the form of a compressed gas (i.e., pneumatic force) or a pressurized liquid (i.e., hydraulic force) may be used. An hydraulic force may be developed by applying a pressurized gas to the surface of a liquid. The liquid could then exert an hydraulic force on the piston 14 to inject the intraosseous needle assembly 12. The piston 14 may be part of or driven by an electromechanical device such as a solenoid. Alternatively, a handle, lever, or other method for applying manual force to the piston 14 may be utilized. The piston 14 may also be spring driven, or displaced by the force generated by a chemical reaction. Manual force may be applied with a hammer or mallet striking a hammerhead or other appropriate force-receiving surface. Any driving force sufficient to cause the needle assembly 12 to penetrate the surface of a bone containing marrow may be used with the present invention.

At the time of the invention it would have been obvious to one having ordinary skill in the art to substitute the hydraulic force (which includes a hydraulic cylinder and hydraulic pressure supply) of Kramer into the Young device because Kramer teaches one can substitute a hydraulic force for a spring driven force.

8. Claims 6 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Young ‘316 in view of Green et al. “Green” US 5,314,435. Young discloses all of claim 1, but does not

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state which material the punch comprises or that the punch should be composed of all the same material. Green teaches the step of making the punch out of a polymeric material to make the device cheaper to produce.

Preferably all components of delivery system 10 are fabricated from polymeric materials, which thereby reduces the cost of manufacture of the system and makes it economically feasible to dispose the system after use.

At the time of the invention it would have been obvious to one having ordinary skill in the art to make all the components of the Young device out of a polymeric material because Green teaches making the device completely of polymeric material will reduce the cost of manufacture of the device.

Response to Arguments

Applicant's arguments with respect to claims 1-6, 8-13, 15-17 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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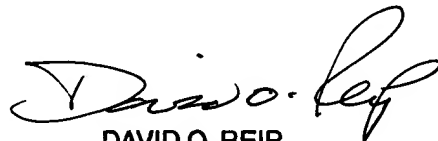
CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul A Roberts whose telephone number is (703) 305-7558. The examiner can normally be reached on 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on 703-308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Paul Roberts
July 21, 2003


DAVID O. REIP
PRIMARY EXAMINER